UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/319,541	08/19/1999	RAINER H. MULLER	62-659-50781	3247

20736 7590 02/12/2003

MANELLI DENISON & SELTER
2000 M STREET NW SUITE 700
WASHINGTON, DC 20036-3307

EXAMINER	
SHARAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/319,541	Applicant(s) MULLER, RAINER H.	
	Examiner Shahnam Sharareh	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,25 and 31-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,25 and 31-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Amendments filed on Nov 13, 2002 have been entered. Claims 9, 25, 31-49 are pending. Claims 37, 38, and 44 are independent.

Any rejection that is not addressed in this Office Action is considered obviated in view of persuasive arguments.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

2. Claims 37-38, 31-33, 35, 37-49, 9, 25 stand rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al US Patent 5,202,159.

Applicant's arguments in the response filed on Nov 13, 2002 ("The Response") have been fully considered but are not found persuasive. Applicant argues that the spray-dried product by Chen is a microcapsule and a capsule comprise a core and a surrounding wall and the drug is coated with the polymer in the spray-drying process leading to capsule. *The Response*, at page 7. In reply, Examiner states that the scope of the pending claims does not exclude such the microcapsule characteristics of Chen. First of all the process steps used by Chen are substantially the same as the instantly claimed process. *see* col 8, lines 26-42. Second, Chen uses the same material as the instant claims. *Id.* Third, the recitation of particles are not exclusive in the instant specification, rather it is viewed given its broadest reasonable interpretation consistent with art including pellets, granule grains, microparticles etc.. *see specification* at page 1, lines 35-37. Examiner views these matrix units to encompass microcapsules.

Finally, Applicant's statement is merely conclusory void of any scientific or legal evidence. Chen at col 8, line 3-10 describes spray-dried powders of enteric-coated microcapsules. Contrary to applicant's conclusion, Chen does not provide any statement about the relationship between Chen's core, the surrounding wall, and the drug therein. Rather it merely makes a theoretical suggestion that spray-dried powder wee encapsulated in enteric-coated powder. Such argument does not differentiate the scope of the pending claims from the compositions disclosed by Chen, because it is not clear what is herein claimed to be the inventive step or inventive element different from the compositions of Chen. It appears Applicant is arguing that the instant claim composition has the excipient and active substance in a coherent phase and the matrix material incoherent, and further the matrix material provides prolong-release properties. However, such features do not impart patentability, because under the principle of inherency, Chen uses the same process steps and the same precursor materials as the instant claims, thus, at the end the powdered particles of Chen must inherently possess the same physical characteristics as the instantly claimed powdered particles.

Moreover, even the language of the instant claims on its face does not exclude the compositions of Chen. Assuming *arguendo*, that Chen's teaches encapsulation of microcapsules by a polymeric moiety. Subsequently, the excipient and its active substance commingle with each other to form a coherent phase that is ultimately surrounded by a polymeric phase, which as applicant argues, constitutes a coating. See Chen at col 5, lines 20-63. At the end, Chen's microcapsules are compressed to form a tablet. See Chen at col 8, lines 41-44. This shows that the active substance of Chen

and excipient exist in a coherent phase, while the polymeric coating collectively exist in the form of an incoherent matrix within the tablet providing the prolong release properties of the whole tablet. Therefore, on its face the language of instant claims are not different from the compositions thought by Chen.

Applicant then argues that the flowability of the powder by Chen is poor. *The Response*, at page 7. Examiner rejects this argument because it is not commensurate with the scope of the claim. The instant claims are not directed to any degree of flowability therefore such arguments is immaterial to the scope of the pending claims. Nevertheless, Examiner would like to address that no matter what is considered poor, Chen clearly teaches flowable powder capable of retarding drug release below 10% for at least two hours in 0.1 HCl solution, see fig 4, and col 6, lines 20-30 .

Further Applicant appears to selectively disregard Chen's teaching that the flowability of the spray-dried powder improved after incorporating the excipients, *see Chen* at col 3, lines 41-44; col 6, lines 19-20. Chen then later exemplified such statement in its table I and Fig 4-5. The open-ended transitional language of the instant claims does not exclude such features of Chen. In fact, such teachings by Chen is within the scope of the pending claims.

Furthermore, Applicant's arguments the Chen does not provide a prolong release property achieved by the polymeric network or that the instant invention provides a nice matrix release are not persuasive. *The Response*, at page 6 and 8. The instant independent claims are directed to formulations comprising a matrix material phase, an excipient phase, and an active substance phase. Chen discloses methods of preparing

sodium diclofenac enteric coated comprising dissolving sodium diclofenac (active substance) in water to form a solution, then add an amount of excipient to the solution to form a suspension, then add Eudragit L 30D (a polymeric moiety) to the mixture, and finally atomize the slurry to form spray-dried powder. *see abstract*, col. 8-lines 26-55. Chen formulates his powder by using the same components as instantly claimed, in the same concentrations via the same process steps; namely spray-drying *see* col 4, table I, item V. Chen then teaches that the composition made only released 2-11% of the drug, which is considerably slower release behavior than other controls, after up to 5 hours. *see* col 6, lines 60-67. Such release is not that bad after all, assuming, it can be described in a relative fashion. Thus, Chen's powder anticipates the limitations of the instant claims for the same reasons of record.

3. Claims 37-49, 9, 25, 31, 35-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Norling et al US Patent 5,958,458.

Applicants' arguments are considered but are not persuasive. Applicant first argues that the "consisting essentially of "language of claim 37 excludes active drug. This argument is not understood because the instant claim 37 uses the transitional language "comprising" throughout. Thus, the argument is moot on its face.

Applicant further argues that the physical characteristics of Norling's composition are different than those instantly claimed. For example, Applicant continues on the notion that Norlings center is drug-free and the drug is located in the shell and that the drugs within the instant particles are throughout the complete particle matrix. Again,

such features are not claimed and thus are not commensurate with the scope of the pending claims.

Applicant argues that Norling, in contrast to the instant claims, uses inorganic salts. The instant claims do not exclude the use of inorganic salts as essential material in the particles; thus, such arguments are not commensurate with the scope of the claims. Nevertheless, Norling sets forth the use of various organic materials such as theophylline, chloropheniramine and hydrocodone, *see Norling* examples 2-5.

Applicant must consider that for applying prior art under 35 USC 102, "reading a claim in light of the specification, to thereby interpret limitations explicitly recited in the claim, is a quite different thing from `reading limitations of the specification into a claim,' to thereby narrow the scope of the claim by implicitly adding disclosed limitations which have no express basis in the claim. The court found that applicant was advocating the latter, e.g., the impermissible importations of subject matter from the specification into the claim. *In re Prater*, 162 USPQ 541, 550 - 51 (CCPA 1969). See MPEP 2111. Accordingly, attempting to limit the scope of the claim, as Applicant has done here, is not proper.

It is well settled in the patent law that if the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In the instant case, regardless of the intended use of Norling's pellets, Norlings's post spray-drying particles of pellets meets the size limitations, the

physical and chemical limitations of the instant formulations and method claims, because they meet all the elements of the instantly claimed formulations and method steps for the reasons of record. *See Norling's* claims 1-5, 20.

Applicant further argues that the pellets of Norling and the instant polymer-compounds are not similar relying on ROMPP Chemielexikon and the Pierre Pelletier, 1788-1842. However, since no such publications or translations thereof are provided, such teachings are not considered.

Finally, Applicants arguments with respect to the Rule 132 Decloration filed on March 1, 2002 have been fully considered, but are not persusive for the reasons set forth in Paper No. 20. The Declaration merely provided anecdotal arguments which were fully addressed in Paper No. 20.

New Grounds of Rejection

4. Claims 9, 25, 31-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen US Patent 5,202, 159 in view of Norling et al US Patent 5,958,458.

The teachings of Chen and Norling et al are discussed above. Both Norling and Bauer teach preparing tablet formulations by directly compressing spray dried powder, thus, their teachings are analogous.

Chen fails to teach particle sizes of 1-630 μm. Norling teaches methods of employing spray-drying process to prepare particle size of 90-225 μm.

Although, Chen does not teach the instant particle sizes, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the process steps as taught by Norling to optimize the size of the final particles by routine

experimentation to provide oral dosage formulations with desirable release properties. The ordinary skill in the art would have been motivated to make such modifications, because as taught by Norling, he would have had a reasonable expectation of success in improving the flowablility and release properties of Chen's formulations when using Norling's particle size.

Information Disclosure Statement

The information disclosure statement filed Nov 13, 2002 fails to comply with 37 CFR 1.97(d) because it lacks the fee set forth in 37 CFR 1.17(p). It has been placed in the application file, but the information referred to therein has not been considered. See MPEP 609.

Conclusion

5. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

ss
February 9, 2003

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200